MAR 1 4 2013

510(k) SUMMARY
AS REQUIRED BY SECTION 807.92(C)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92(C)

The Assigned 510(k) number is: k122907

Date of Summary: March 12th, 2013

Common Name: hCG (Human Chorionic Gonadotropin) Pregnancy Midstream Test

Regulatory Information:

1. Regulation section: 21 CFR § 862.1155, Human Chorionic Gonadotropin (HCG) test system
2. Classification: Class II
3. Product Codes: LCX – Kit, test, pregnancy, hCG, Over-the-Counter
4. Panel: Clinical Chemistry (75)

Applicant and Initial Importer:

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Contact Persons:

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Identification / Product Name:
Fastep™ At-Home Pregnancy Tests

Description:
Polymed Therapeutics' Fastep™ At-Home Pregnancy Test utilizes monoclonal antibody reagents to selectively detected elevated levels of hCG in urine specimen at the sensitivity of 20mIU/mL. It is designed to be tested in midstream and dipstick mode. The Fastep™ At-Home Pregnancy Test consists of a single test strip encased in plastic device housing, with an absorbent tip. The result is generated by immersing the tip in the urine stream or urine cup for a sufficient amount of time to absorb an adequate sample volume. Each test reagent strip consists of a mouse monoclonal anti-α-hCG antibody coated membrane and a dried chemical pad containing mouse monoclonal anti-β-hCG anybody colloidal gold conjugate. The control antibodies are goat anti-mouse IgG.

Intended Use:
The Polymed Therapeutics' Fastep™ At-Home Pregnancy Test is a rapid chromatographic immunoassay for the visual, qualitative detection of human chorionic gonadotropin (hCG) in urine specimen to help in the early determination of pregnancy, intended to be distributed for over-the-counter (OTC) setting.

Substantial Equivalence (Predicate Kit):
Teco Diagnostics One-Step Midstream Pregnancy Test is used as predicate device for Polymed Therapeutics' At-Home Pregnancy Test to compare their performance of required studies. The clinical urine specimens used for midstream and dipstick accuracy study were confirmed indirectly through quantitative hCG measurements.

510(k) numbers for predicate device is:
Teco Diagnostics One-Step Midstream Pregnancy Test (k974059)

Performance:
The product performance characteristics of Polymed Therapeutics' Fastep™ At-Home Pregnancy Test were assessed through internal and external performance studies and evaluation. An accuracy (consumer) study was performed using 148 lay users, indicating a minimum of 92.7% agreement compared with Teco Midstream Pregnancy Test (k974059) and 100% agreement compared with confirmed hCG quantitative level of tested specimens.

An additional lay user study was performed to demonstrate that intended users can correctly interpret test results with hCG concentrations around the cutoff level of the device (20 mIU/ml). 21 laypersons performed the study, each testing the "dipstick" mode by following the testing and reading result instructions of our package insert, and indicated 100% agreement compared with confirmed hCG quantitative level of tested specimens.

Conclusion:

The results of evaluated studies demonstrate the substantial equivalency between Polymed Therapeutics' Fastep™ At-Home Pregnancy Test and the Predicate kit. It is demonstrated that Polymed Therapeutics' Fastep™ At-Home Pregnancy Test is safe and effective in detecting human chorionic gonadotropin (hCG) in urine sample to aid in the early determination of pregnancy, it is easy to use and interpret result by the lay users. Additionally, it is demonstrated that the Fastep™ At-Home Pregnancy Test are able to be clearly understood and accurately interpreted by laypersons at near-cutoff level concentrations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 14, 2013

Polymed Therapeutics, Inc.
c/o Feng-Yu Lee
IVDD Regulatory Consultant
27001 La Paz Rd, Suite 266B
Mission Viejo, CA 92691

Re: k122907
Trade/Device Name: Fastep™ At-Home Pregnancy Tests
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: II
Product Code: LCX
Dated: January 31, 2013
Received: February 07, 2013

Dear Feng-Yu Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k122907

Device Name: Fastep™ At-Home Pregnancy Tests

Indications for Use:

The Polymed Therapeutics' Fastep™ At-home Pregnancy Test is a rapid chromatographic immunoassay for the visual, qualitative detection of human chorionic gonadotropin (hCG) in urine specimen to aid in the early detection of pregnancy.

Polymed Therapeutics' FastepTM At-Home Pregnancy Test is intended to be distributed for Over-the-Counter (OTC) use.

Prescription Use _____ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use _X_. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
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Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k122907